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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-------------------------|--------------------------------|----------------------|---------------------|------------------|
| 10/618,088 | 07/14/2003 | Elizabeth Jaffee | 001107.00363 | 4098 |
| 22907 BANNER & W | 7590 06/01/201 TTCOFF, LTD. | EXAMINER | | |
| 1100 13th STR | | GUSSOW, ANNE | | |
| SUITE 1200 WASHINGTO | N, DC 20005-4051 | | ART UNIT | PAPER NUMBER |
| | | | 1643 | |
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| | | | MAIL DATE | DELIVERY MODE |
| | | | 06/01/2010 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief

| Application No. | Applicant(s) | |
|-----------------|---------------|--|
| 10/618,088 | JAFFEE ET AL. | |
| | | |
| Examiner | Art Unit | |

| | ANNE M. GUSSOW | 1643 | |
|--|---|---|--|
| The MAILING DATE of this communication appe | ears on the cover sheet with the c | correspondence add | ress |
| THE REPLY FILED <u>13 May 2010</u> FAILS TO PLACE THIS APP | LICATION IN CONDITION FOR AL | LOWANCE. | |
| 1. The reply was filed after a final rejection, but prior to or on application, applicant must timely file one of the following application in condition for allowance; (2) a Notice of Appel for Continued Examination (RCE) in compliance with 37 Comperiods: | replies: (1) an amendment, affidavit eal (with appeal fee) in compliance | t, or other evidence, w with 37 CFR 41.31; or | hich places the (3) a Request |
| a) The period for reply expires <u>4</u> months from the mailing date | of the final rejection. | | |
| b) The period for reply expires on: (1) the mailing date of this A no event, however, will the statutory period for reply expire to Examiner Note: If box 1 is checked, check either box (a) or (MONTHS OF THE FINAL REJECTION. See MPEP 706.07(| ater than SIX MONTHS from the mailing b). ONLY CHECK BOX (b) WHEN THE | g date of the final rejection | n. |
| Extensions of time may be obtained under 37 CFR 1.136(a). The date have been filed is the date for purposes of determining the period of extunder 37 CFR 1.17(a) is calculated from: (1) the expiration date of the set forth in (b) above, if checked. Any reply received by the Office later may reduce any earned patent term adjustment. See 37 CFR 1.704(b). NOTICE OF APPEAL | tension and the corresponding amount of shortened statutory period for reply origing than three months after the mailing date | of the fee. The appropria nally set in the final Offic | ate extension fee e action; or (2) as |
| 2. The Notice of Appeal was filed on A brief in comp filing the Notice of Appeal (37 CFR 41.37(a)), or any exter Notice of Appeal has been filed, any reply must be filed w AMENDMENTS | nsion thereof (37 CFR 41.37(e)), to | avoid dismissal of the | |
| 3. The proposed amendment(s) filed after a final rejection, by | out prior to the date of filing a brief | will not be entered be | cause |
| (a) They raise new issues that would require further con | nsideration and/or search (see NOT | | |
| (b) They raise the issue of new matter (see NOTE belo | | | |
| (c) ☐ They are not deemed to place the application in bet appeal; and/or | ter form for appeal by materially rec | lucing or simplifying ti | ne issues for |
| (d) ☐ They present additional claims without canceling a | corresponding number of finally reje | ected claims. | |
| NOTE: (See 37 CFR 1.116 and 41.33(a)). | | II (A) 1 (() | TOL 004) |
| The amendments are not in compliance with 37 CFR 1.12 Applicant's reply has overcome the following rejection(s): | | mpliant Amendment (I | 310L-324). |
| 6. ☐ Newly proposed or amended claim(s) would be all | | imely filed amendmer | t canceling the |
| non-allowable claim(s). | | | |
| 7. For purposes of appeal, the proposed amendment(s): a) how the new or amended claims would be rejected is prove The status of the claim(s) is (or will be) as follows: | | l be entered and an e | kplanation of |
| Claim(s) allowed: | | | |
| Claim(s) objected to: Claim(s) rejected: <u>26,38,115 and 122-126</u> . | | | |
| Claim(s) withdrawn from consideration: | | | |
| AFFIDAVIT OR OTHER EVIDENCE | | | |
| The affidavit or other evidence filed after a final action, bu because applicant failed to provide a showing of good and was not earlier presented. See 37 CFR 1.116(e). | | | |
| The affidavit or other evidence filed after the date of filing entered because the affidavit or other evidence failed to o showing a good and sufficient reasons why it is necessary | vercome <u>all</u> rejections under appea | ıl and/or appellant fail: | s to provide a |
| 10. | n of the status of the claims after er | ntry is below or attach | ed. |
| The request for reconsideration has been considered bu <u>See Continuation Sheet.</u> | t does NOT place the application in | condition for allowan | ce because: |
| 12. ☑ Note the attached Information <i>Disclosure Statement</i> (s). (13. ☐ Other: | (PTO/SB/08) Paper No(s). <u>4/9/10</u> | | |
| | /Anne M. Gussow/ Examiner, Art Unit 1643 | | |

Continuation of 5. Applicant's reply has overcome the following rejection(s): Applicant's arguments have overcome the objection to claim 126 regarding the Markush group.

Continuation of 11. does NOT place the application in condition for allowance because:

Applicant's arguments filed May 13, 2010 have been carefully considered by the examiner, but are deemed not to be persuasive.

Regarding the 112 indefinite rejection, the examiner agrees that dependent claims 124 and 125 require a second polypeptide, however, the independent claims, when read separate from claims 124 and 125, do not require a second polypeptide. Each claim is examined on it's merits, not a claim set as a whole. Therefore, claims 26, 38, 115, 122, 123, and 126 are indefinite for the reasons of record.

Regarding the 112 written description rejection, the specification discloses fusion peptides comprising a first pepide fused to a second peptide. The specification does not disclose compositons comprising more than one peptide. Applicant's citation of "a repeated series of an epitope sequence or different epitope sequences in a series" does not support more than one peptide - both the repeated series of a single epitope or the series of different epitopes are still a single peptide and the fusion peptide is a single peptide although it contains two parts.

Regarding the 103(a) rejection, with respect to the 'obvious to try' rationale, MPEP 2141 states exemplary rationales that may support a conclusion of obviousness inlcude obvious to try - choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success. In the instant case, it was known in the art that mesothelin protein is overexpressed in a number of cancer types. Thus, treatment involving targeting the overexpressed mesothelin protein would be obvious because Argani teach that mesothelin is a promising target for immunotherapy for those malignancies. Since the art teaches mesothelin as a target for immunotherapy, applicant's arguments regarding immune tolerance of other proteins appear to be misplaced. While immune tolerance is relevant to the general state of the immune art, in this instance, Argani is teaching that mesothelin is a specific target for immunotherapy. Therefore, for these and the reasons of record, the rejection is maintained.